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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,883	07/31/2003	Daniel Kahne	PUAM-0257	1801
23377	7590	12/29/2005	EXAMINER	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103			PONNALURI, PADMASHRI	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/631,883	Applicant(s) KAHNE ET AL.	
	Examiner Padmashri Ponnaluri	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-41,50-57,74-82 and 102-116 is/are pending in the application.
- 4a) Of the above claim(s) 39-41,50-57 and 74-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-38, 102-116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. NOTE the change of Examiner in this application.
2. The amendment and the response filed on 9/27/05 has been fully considered and entered into the application. The amendment filed on 8/31/05 has been considered as non-responsive, however the response filed on 8/31/05 has been considered.
3. Claims 2, 4 and 13 have been canceled by the amendment filed on 9/27/05.

Status of the Claims

4. Claims 1, 3, 5-12, 14-41, 50-57, 74-82 and 102-116 are currently pending.
5. Claims 39-41, 50-57 and 74-82 are withdrawn from consideration as being directed to a nonelected invention.
6. Claims 1, 3, 5-12, 14-38 and 102-116 are under consideration.

Election/Restriction

7. Claims 39-41, 50-57 and 74-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
8. The elected species was not found; accordingly the search was extended to include other species within the scope of the generic claims (e.g. claim 1 and 102).
9. This application contains claims 39-41, 50-57 and 74-82 drawn to an invention nonelected with traverse in Paper filed on 12/16/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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Specification/ Priority

10. The amendment to the specification filed on 8/31/05 has been considered and entered into the application.

Withdrawn Claim Rejections/Objections

11. The following 35 USC. 112, second paragraph rejections of claims 1-38, 102-116 have been withdrawn in view of the amendments.

- a) the rejection of claims (A-B) as lacking metes and bounds of term 'modified alpha amino acid residue';
- b) the rejection of the term 'modified disaccharide' as being indefinite ©;
- c) the rejection for omitting structural feature (D);
- d) the metes and bounds of the term 'glycosidic groups' and 'sugar residues' (E);
- e) the rejection of the term 'modified to bear at least one substituent which is not hydroxyl' in claim 102, (G).

12. The rejection of claims 1-6, 9-15, 18-27 and 30-38 under 35 U.S.C. 102(e) as being anticipated by Ge et al., Science Vol. 284 (April 16, 1999) has been withdrawn, since the instant application gets the priority date of provisional application 60/150,690 filing date of 7/14/98.

13. The rejection of claims 1-38 and 102-116 under 35 U.S.C. 102(e) as being anticipated, or alternatively rendered obvious over Kahne, WO 00/42067, has been withdrawn since the instant application gets the priority date of provisional application 60/150,690 filing date of 7/14/98.

14. The rejection of claims 1, 102 and 103 under 35 U.S.C. 102(a,b) as being anticipated by Stack et al. EP 0802199A2 (10/22/97) has been withdrawn in view of the amendments to the claims.

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15. The rejection of claims 1, 102 and 103 are rejected under 35 U.S.C. 102(e) as being anticipated by Cooper et al. US Pat. No. 5,843,889 (12/1998) has been withdrawn in view of the amendments to the claims.

Maintained Claim Objection (s) and/or Rejection (s)

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

17. The rejection of claims 102, 107 and dependent claims as the term 'substituted amino groups' lack metes and bounds' (paragraph F) has been maintained for the reasons set forth in the previous office action.

18. The scope enablement rejection of claims 1-38, 102-116 set forth in the previous office action (3/28/05) has been maintained for the reasons f record.

19. The lack of written description rejection set forth in the previous office action (3/28/05) has been maintained for the reasons f record.

20. The obviousness-type double patenting rejection of claims 1-38 and 102-116 over claims 1-47 (especially claims 9 and 14 and claims dependent thereon) of U.S. Patent No. 6,498,238 (12/02) has been maintained for the reasons of record.

21. The obviousness-type double patenting rejection of claims 1-38 and 102-116 over claims 1-19 of U.S. Patent No. 6,841,661 (1/05) has been maintained for the reasons of record.

22. The obviousness-type double patenting rejection of claims 1-38 and 102-116 over claims 1-20 of U.S. Patent No. 6,710,168 (3/04) has been maintained for the reasons of record.

New Claim Rejections Necessitated by the Amendment

23. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

24. Claims 1, 3-38, 102-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

25. Claim 1 recites the limitation "the substituents of formula YXR " in line 33 (page 3 of the amendment). There is insufficient antecedent basis for this limitation in the claim.

Claims 1, 102 are vague and indefinite, and there are no metes and bounds of the claim limitations. Claims 1 and 102 are indefinite by reciting 'at least one of the substituent', 'two or more of substituents.' From the claim recitation it is not clear how many substituents are present and the position of the substituents, and the what is the formula of substituents.

Claim 102 recites the limitation "the substituents of formula YXR" in line 10. There is insufficient antecedent basis for this limitation in the claim.

26. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

27. Claim 1 and dependent claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

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The instant amended claim 1 recites that ‘a disaccharide having a glucose residue directly attached to said A4 residue, wherein the glucose residue bears an N-substituted aminohexose residue, and at least one substituent of the formula’ Thus, according to the amended claim the glucose residue of the disaccharide which is directly attached to the A4 residue bears N-substituted aminohexose and at least one substituent of the formula

However, the specification as filed and the original claims, recite that the first glucose bears ‘a substituted amino or unsubstituted amino group’; and the second of said saccharide bears at least one substituent of the formula ... (see original claims 102-103).

Now the amended claim 1 recites that the glucose attached to the A4 residue has amino hexose group and further has at least one substituent of formula Thus, the newly added claim 1 is different in scope compare to the original claims.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

Response to Arguments

28. *F. In claims 102, 107 (and dependent claims), the term “substituted amino group” lacks metes and bounds regarding the encompassed substituents and the ultimate structure.*

29. Applicant's arguments filed on 9/27/05, regarding the rejection of claims 102, 107 (F) as being indefinite have been fully considered but they are not persuasive.

Applicant's response has not addressed the ‘substituted amino group.’ According to the amendment the first saccharide has amino or substituted amino group. However the claim does not further recite how the amino group on the first saccharide is substituted.

Claims 1-38 and 102-116 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for vancomycin glucose C6 substituted derivatives of original claims 83-101 (and as described in specification table on pages 134-135), the specification does not reasonably provide enablement for the full scope of glycopeptides or glycopeptide antibiotics of claims 1 and 102 (and claims dependent thereon). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. .

The factors to be considered in a determination of undue experimentation are disclosed in In re Wands (USPQ 2d 1400: CAFC 1988) which include: a. The breadth of the claims. b. The nature of the invention; c. The state of the prior art; d. The level of one of ordinary skill e. The level of predictability in the art; f. The amount of direction provided by the inventor; g. The presence or absence of working examples; h. The quantity of experimentation necessary needed to make or use the invention based on the disclosure; See :In re Wands USPQ 2d 1400 (CAFC 1988).

The breadth of the claims

The breadth of potential glycopeptides of different chemical structure as encompassed by claims 1 and 102 is huge in light of the failure to specifically claim the linkage and position between the peptide and glycoside portions of the glycopeptide as well as the failure to specifically claim the metes and bounds regarding the chemical nature of the peptide (e.g. the nature of alpha amino acids and the position of the covalent bond) and glycoside portions as well as substituents therefrom for example as described in the indefinite rejection above:

A. In claim 1 (and dependent claims) the term (s) "modified alpha amino acid residue" lacks metes and bounds as to the modifications and resulting structure encompassed by the claimed invention.

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B. in claim 1 (and dependent claims) the term “modified amino acid residue” as defined in multiple instances in the specification page 17 as including (e.g. comprising) “groups easily introduced” (e.g. substituents) is a relative term which renders the claim indefinite. The term “easily introduced” is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

C. In claims 1, 2, 102, 103 (and dependent claims) the metes and bounds of “modified disaccharide” (“disaccharide modified to bear”) regarding what chemical portion of the saccharide is being modified and (with respect to claim 1) which sugar residue(s) are being modified.

D. Claim 1 (and dependent claims) is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are where (e.g. what part of the modified/unmodified alpha amino acids; and what part of the glycosyl group) the “glycosidic bond” is formed between the peptide and glycosyl group (s) to form the glycopeptide.

E. Claim 1 (and dependent claims) is rejected since there is no metes and bounds regarding the upper limit (e.g. “one or more”) of the “glycosidic groups” and “sugar residues” nor the chemical structure e.g. the metes and bounds of “glycosidic groups” and “sugar residues” within the scope of the presently claimed invention.

F. In claims 102, 107 (and dependent claims), the term “substituted amino group” lacks metes and bounds regarding the encompassed substituents and the ultimate structure.

G. In claim 102 (and dependent claims), the term “modified to bear at least one substituent which is not hydroxyl” lacks metes and bounds regarding the encompassed substituents and ultimate structure.

The nature of the Invention/State of the Prior art

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The present invention is directed to the making and screening of glycopeptide antibiotics; although it is noted that claims 1 and 102 are not so limited. Additionally, it is noted that "the nature and placement of the sugars on the glycopeptide antibiotics play critical roles in antibiotic activity". In this regard it is further noted that, "that there have been no reports of modification on the glucose residues of vancomycin which have affected activity" E.g. see specification page 7, first full paragraph.

The level of one of ordinary skill

The level of one of ordinary skill in the art is masters or PhD level.

The level of predictability in the art

*The sugar residues of the vancomycin and other glycopeptide antibiotics have been shown to affect binding activities e.g. "the nature and placement of the sugars on the glycopeptide antibiotics play critical roles in antibiotic activity". Additionally, structural changes in the sugar residues can produce significant changes in antibiotic activity. See e.g. specification page 4, first full paragraph. Accordingly, the making and potential usefulness of "glycopeptide" compounds of different chemical structure is not a priori predictable. Courts have recognized that reaction steps or compound structure which is shown to be (e.g. by applicant or prior art) to be critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976); *Ex parte Bhide* (BdPatApp&Int) 42 USPQ2d 14.*

The amount of direction/working examples

The specification only provides guidance and examples directed to the making and use (e.g. antibiotic) of vancomycin glucose C6 substituted derivatives of claims 83-101 which share a common structure which is not representative of the scope of claimed glycopeptides .

Quantity of Experimentation

In light of the unpredictability surrounding the making and use of glycopeptide derivatives of diverse structure which possess antibiotic activity, the undue breadth of the claimed invention, the lack of

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adequate guidance regarding the making and antibiotic testing of a representative sample of glycopeptides, the lack of metes and bounds regarding claimed substituents, the lack of critical/essential core structure, one wishing to practice the presently claimed invention would be unable to do so without engaging in undue experimentation.

30. Applicant's arguments filed on 9/27/05 (amendments) and 8/31/05, regarding the scope of enablement rejections have been fully considered but they are not persuasive.

Applicants traverse the rejection. Applicants argue that the present amendment focuses to certain preferred embodiments. The pending claims are both as clear as the complex technology permits and fully enabled.

Applicant's arguments have been fully considered and are not persuasive. The breadth of the claims is huge. And metes and bounds of the number of substituents, position of substituents is not clear. The glucose residue attached to the A4 residue bears at least one substituent of either formula YXR, $N+(R1)=CR2R3$, $N=PR1R2R3$, $N'+R1R2R3$ or $P+R1R2R3$. And further the claim recites that there may be more than one substituent. And do not recite the position of the substituents. Thus, the amended claim breadth is indefinite.

The specification only provides guidance and examples directed to the making and use of vancomycin C6 substituted derivatives, which share a common structure. The specification lacks adequate guidance regarding the making of the antibiotics of the instant claims. Thus, for the reasons of record, and for the reasons set forth in the present office action the rejection has been maintained.

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31. *Claims 1-38 and 102-116 are rejected under 35 U.S.C.112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (Lack of Written Description).*

It is first noted that written description is legally distinct from enablement: "Although the two concepts of are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures the that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention." See 1242 OG 169 (January 30, 2001) citing University of California v. Eli Lilly & Co

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1405 (1997), quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in University of California v. Eli Lilly defined the invention by function of the claimed DNA (encoding insulin)].

The present invention is directed to the making and screening of glycopeptide antibiotics; although it is noted that claim 1 is not so limited. The breadth of potential glycopeptides of different chemical structure as encompassed by claims 1 and 102 (especially claim 1) is huge in light of the failure to specifically claim the linkage and position between the peptide and glycoside portions of the glycopeptide as well as the failure to specifically claim the metes and bounds regarding the chemical

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nature of the peptide (e.g. the nature of alpha amino acids and the position of the covalent bond) and glycoside portions as well as substituents therefrom; for example

A. In claim 1 (and dependent claims) the term (s) "modified alpha amino acid residue" lacks metes and bounds as to the modifications and resulting structure encompassed by the claimed invention.

B. in claim 1 (and dependent claims) the term "modified amino acid residue" as defined in multiple instances in the specification page 17 as including (e.g. comprising) "groups easily introduced" (e.g. substituents) is a relative term which renders the claim indefinite. The term "easily introduced" is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

C. In claims 1, 2, 102, 103 (and dependent claims) the metes and bounds of "modified disaccharide" ("disaccharide modified to bear") regarding what chemical portion of the saccharide is being modified and (with respect to claim 1) which sugar residue(s) are being modified.

D. Claim 1 (and dependent claims) is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are where (e.g. what part of the modified/unmodified alpha amino acids; and what part of the glycosyl group) the "glycosidic bond" is formed between the peptide and glycosyl group (s) to form the glycopeptide.

E. Claim 1 (and dependent claims) is rejected since there is no metes and bounds regarding the upper limit (e.g. "one or more") of the "glycosidic groups" and "sugar residues" nor the chemical structure e.g. the metes and bounds of "glycosidic groups" and "sugar residues" within the scope of the presently claimed invention.

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F. In claims 102, 107 (and dependent claims), the term "substituted amino group" lacks metes and bounds regarding the encompassed substituents and the ultimate structure.

G. In claim 102 (and dependent claims), the term "modified to bear at least one substituent which is not hydroxyl" lacks metes and bounds regarding the encompassed substituents and ultimate structure.

Additionally, it is noted that "the nature and placement of the sugars on the glycopeptide antibiotics play critical roles in antibiotic activity" .. Additionally, structural changes in the sugar residues can produce significant changes in antibiotic activity. See e.g. specification page 4, first full paragraph. Accordingly, the making and potential usefulness of "glycopeptide" compounds of different chemical structure is not a priori predictable.

In support of such a broad genus, in an unpredictable art area, the specification only provides guidance and examples directed to the making and use (e.g. antibiotic) of vancomycin glucose C6 substituted derivatives of original claims 83-101 which share a common structure which is not representative of the scope of claimed glycopeptides . Such a narrow scope of examples fail to provide specification support for the claiming of such broad compound genera.

32. Applicant's arguments filed on 9/27/05 (amendment) and 8/31/05 (response), ~~regarding the lack of written description rejection~~ have been fully considered but they are not persuasive.

Applicants have not addressed lack of written description rejection of record. It has been noted that the requirement for written description is legally distinct from enablement. The rejection has been maintained in absence of response from applicants.

33. *Claims 1-38 and 102-116 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47 (especially claims 9 and 14 and claims dependent thereon) of U.S. Patent No. 6,498,238 (12/02). Although the conflicting claims are not*

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identical, they are not patentably distinct from each other because the patent claim generic of compounds are within the scope of the presently claimed broader genus (e.g. the patent claims dalbaheptapeptide derivatives which are vancomycin derivatives), as are the claimed patent species.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Pat. No. 6,498,238, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

34. *Claims 1-38 and 102-116 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,841,661 (1/05). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claim generic of compounds are within the scope of the presently claimed broader genus (e.g. the patent claims dalbaheptapeptide derivatives which are vancomycin derivatives) as are the claimed patent species.*

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A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

35. *Claims 1-38 and 102-116 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,710,168 (3/04). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims teach compound species which are clearly within the scope of the presently claimed invention.*

36. Applicant's arguments filed on 9/27/05 (amendment) and 8/31/05 (response), regarding the Obviousness-type double patenting rejection of claims over US Patents 6,498,238; 6,841,661; and 6,710,168 have been fully considered but they are not persuasive.

Applicant's confirmation of the assignee of these patents is same as the current application have been considered. However, applicants traverse the rejections over the commonly owned patent claims. Applicants recite that the instant claims are focused on certain preferred embodiments, together with the extensive exemplification of the specification, that the present claims are not rendered obvious in view of the issued claims of the '238, 661 or 168 patents.

Applicant's arguments and assertions have been considered and are not persuasive, because the instant claims are broad genus, and the reference claims are to species encompassing the genus.

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For example, US Patent 6,498,238 and 6,841,661 claims are drawn to vancomycin analog whose glucose C-6 position is modified to bears polar substituent, which clearly reads on the instant claim glycopeptide, in which a disaccharide having a glucose bearing an N-substituted amino hexose residue, and at least one substituent.

US Patent 6,710,168 claims are drawn to specific vancomycin compounds which includes the specifically elected 'glucose-C6-amine vancomycin. Thus, the reference claims are obvious over the instant claimed glycopeptides.

Thus, for the reasons of record the rejections of record have been maintained.

Conclusion

37. No claims are allowed.

38. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


PADMASHRI PONNALURI
PRIMARY EXAMINER

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

22 December 2005